



## 5 FORMULA:

<i>Ingredients</i>	<i>Amt/unit (mg)</i>
<b>LOADING</b>	
Naltrexone HCl	5.0
Sugar Spheres (30/35 mesh)	50.0
Opadry White Y-5-7068	2.5
Purified Water	42.5*
<b>OVERCOATING</b>	
Opadry White Y-5-7068	3.02
Purified Water	17.11*
<b>NON-RELEASE COATING (FOR RENDERING OPIOID ANTAGONIST SUBSTANTIALLY NON-RELEASABLE)</b>	
Eudragit RS30D (dry wt.)	12.10
Triethyl Citrate	2.42
Talc	4.84
Purified Water	49.21*
<b>OVERCOATING</b>	
Opadry White Y-5-7068	4.12
Purified Water	23.35*
<b>Total</b>	<b>84.0</b>

\* Remains in product as residual moisture only.

## 10 PROCESS:

1. Solution Preparation Dissolve the Naltrexone HCl in Purified Water. Once dissolved, add the Opadry White and continue mixing until a homogeneous dispersion is yielded.
- 15 2. Loading Apply the above dispersion onto the Sugar Spheres using a fluid bed coating machine.
3. Overcoating Prepare an overcoating solution by dispersing Opadry White in Purified Water. Apply this dispersion over the sugar spheres loaded with Naltrexone HCl using a fluid bed coating machine.
- 20 4. Retardant Coating Prepare the non-release coating solution by mixing the Eudragit RS30D, Triethyl Citrate, Talc, and Purified Water. Apply this dispersion over the loaded and overcoated sugar spheres using a fluid bed coating machine.
5. Overcoating Prepare a second overcoating solution by dispersing Opadry White in Purified Water. Apply this dispersion over the non-release coated naltrexone spheres using a fluid bed coating machine.
- 25 6. Curing Cure the spheres at 45°C for approximately 48 hours.